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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,528	01/25/2001	Joseph A. Hedrick	DX0725K2B	7799

7590 10/29/2003

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EXAMINER
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KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/770,528	<b>Applicant(s)</b> HEDRICK ET AL.	
	<b>Examiner</b> Elizabeth C. Kemmerer, Ph.D.	<b>Art Unit</b> 1646	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 16 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: please see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 7-9 and 20-25.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

### **ATTACHMENT TO ADVISORY ACTION**

The rejection of claims 7-9 and 20-25 under 35 U.S.C. §§ 101 and 112, first paragraph, is maintained.

Applicant's arguments (response received 16 October 2003) have been fully considered but are not found to be persuasive for the following reasons. Applicant argues that the Office has adopted an incorrect standard in requiring certain and exact evidence, i.e., that IL-1 $\delta$  is upregulated in psoriasis. Applicant urges that the specification discloses that IL-1 $\delta$  plays a role in inflammation. Applicant reasons that, since not all cytokines play a role in inflammation, that this is a specific asserted utility. This is not found to be persuasive. Inflammation is a common, yet complex, response in the body. Although it is true that not all cytokines are involved in inflammation, it is also true that a diverse array of compounds and environmental stimuli are involved in inflammation. For example, exposure to a cytokine, lye, or a scratch, can lead to an enhanced inflammatory response. Exposure to a cytokine, aspirin, or ice can suppress an inflammatory response. Thus, a very broad class of compounds and environmental stimuli "play a role" in inflammation. An assertion that a new molecule "plays a role" in inflammation is thus not a specific assertion of utility. Post-filing date evidence has shown that the claimed IL-1 $\delta$  is upregulated in psoriasis. This is a very specific activity; unfortunately, it is not asserted in the specification as originally filed.

Applicant argues that there is no requirement to identify a specific type of inflammation or to predict the specific effects of IL-1 $\delta$  in inflammation. Applicant urges that the threshold for utility is not high, and that only a minimal utility is required. This is

Art Unit: 1646

not found to be persuasive, because the minimal threshold of a well-established, or a specific, substantial and credible utility has not been met. As explained above, an assertion that a new compound "plays a role" in inflammation is not specific. Also, since significant further research would have been required to determine what the role was, the assertion is not substantial

Applicant refers to Debets and Kumar, of record. These arguments have been presented previously and are not found to be persuasive for reasons of record.

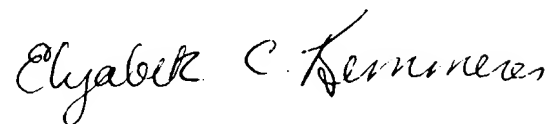
Thus, for the reasons given above and for reasons of record, the rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ECK



ELIZABETH KEMMERER  
PRIMARY EXAMINER